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| 10/527,941                  | 09/23/2005  | Naum Goldstein       | 104599-2                 | 2406             |
| 27388                       | 7590        | 10/20/2008           | EXAMINER                 |                  |
| NORRIS, MCLAUGHLIN & MARCUS |             |                      | LEA, CHRISTOPHER RAYMOND |                  |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                              |                                       |   |
|------------------------------|---------------------------------------|---|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/527,941  | <b>Applicant(s)</b><br>GOLDSTEIN ET AL. |
|                              | <b>Examiner</b><br>Christopher R. Lea | <b>Art Unit</b><br>4161                 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-17 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) 1-17 is/are rejected.  
 7) Claim(s) 7 and 8 is/are objected to.  
 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date 06/28/2009   | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

This application is a 371 (national stage application) of PCT/DE03/03376.

Claims 1-17 are pending. Claims 1-17 are currently under examination.

***Priority***

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Information Disclosure Statement***

2. The information disclosure statement(s) (IDS) submitted on June 28, 2005, was filed before the mailing date of the first office action on the merits. The submission is in compliance with the provisions of 37 CFR 1.97 & 1.98. Accordingly, the information disclosure statement is being considered by the examiner.

***Specification***

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to provide support for the "liposomes and/or nanosomes" in claim 13, "auxiliary substances" in claim 15, or "stabilizers, antioxdants, pH regulators, osmo-regulators or antimicrobial substances" in claim 16.

***Claim Objections***

4. Claims 7 & 8 are objected to because of the following informalities: Neither claim 7 nor 8 express a complete thought, hence they are not sentences. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "... potentiating the efficacy ..." which is indefinite. The efficacy of what is being potentiated? The antecedent is unclear. For purposes of examination, examiner will assume that the efficacy of the "active ingredients affecting the central nervous system" is intended. Since claims 2-17 depend from claim 1, claims 2-17 are also rejected under 35 U.S.C. 112, 2<sup>nd</sup> paragraph.

Claim 2 recites "drug-like substances" which is indefinite. How similar to a drug does a compound have to be considered "drug-like"? Claim 2 also recites "different types of metabolites" which is indefinite. Exactly which "types of metabolites" are included in this? Which are excluded? Claim 2 also recites "such substances of a chemical nature" which is indefinite. Which substances are excluded by this? The metes and bounds of this claim are unascertainable.

Claim 4 recites "hydrate clusters" which is indefinite. This term is not recognized by the art and not defined by the specification.

Claim 5 recites "precursors or reaction products" which is indefinite. Which compounds are included in these groups? N<sub>2</sub> is a possible reaction product of NO, is this substance included?

Claim 6 recites "derivates" which is indefinite. Which compounds are included in these groups? CO<sub>2</sub> is a possible derivate of eicosatric acid, is this substance included? Regarding claim 6, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 8 recites a concentration without a unit; as such the metes and bounds of this claim are unascertainable.

Claim 10 recites the limitation "metabolite" in line 2. There is insufficient antecedent basis for this limitation in the claim. Examiner will treat this claim as though it was dependent not from claim 1, but from claim 2 where antecedent support may be found.

Claim 11 recites the limitation "drug substances" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Examiner will treat this claim as though it was dependent not from claim 1, but from claim 2 where antecedent support may be found.

Claim 12 recites the limitation "metabolite" in line 1. There is insufficient antecedent basis for this limitation in the claim. Examiner will treat this claim as though

it was dependent not from claim 1, but from claim 2 where antecedent support may be found.

Claim 14 recites the limitation "the solution" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim. Examiner is unable to find support for this limitation in any of the other claims.

Claim 16 recites the limitation "auxiliary substances" in line 2. There is insufficient antecedent basis for this limitation in the claim. Examiner will treat this claim as though it was dependent not from claim 1, but from claim 15 where antecedent support may be found.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As stated above "hydrate clusters" in claim 4 is not an art-recognized term; however, one possible interpretation is that applicant was claiming a polymorph crystal form known as a "hydrate." This rejection is based on that interpretation.

***Determination of Claim Scope***

Claim 4 of the instant application claims a pharmaceutical composition comprising an active agent and a substance active in the nasal mucous membrane selected from the Markush group of perhydroxyl radicals, hydrogen peroxide, hydroperoxide radicals or their hydrates clusters.

***Review of Applicants' Disclosure***

The instant specification does not disclose, to which hydrates of perhydroxyl radicals, hydrogen peroxide, or hydroperoxide radicals to which applicants are referring. Applicants' specification does not disclose how to make any particular hydrate of perhydroxyl radicals, hydrogen peroxide, or hydroperoxide radicals, nor do applicants depict chemical structures of perhydroxyl radicals, hydrogen peroxide, or hydroperoxide radicals as any particular hydrate in their disclosure.

***Possession Based on Ordinary Skilled Artisan's Determination/ State of the Prior Art***

It is generally accepted in the art that the formation of a particular hydrate for a given compound or series of compounds is unpredictable (see Vippagunta et al. "Crystalline Solids," *Advanced Drug Delivery Reviews*, 2001, 48, pp 18), therefore, the generic reference to a hydrate of either perhydroxyl radicals, hydrogen peroxide, or hydroperoxide radicals in the instant specification does not provide adequate written support for claims drawn to any hydrate of these compounds. An ordinary skilled artisan would conclude that applicants were not in possession of any particular hydrate

of any of the compounds of corresponding to perhydroxyl radicals, hydrogen peroxide, or hydroperoxide radicals of the claimed composition. Furthermore, because applicants' generic reference to hydrates of perhydroxyl radicals, hydrogen peroxide, or hydroperoxide radicals does not permit the ordinary skilled artisan to clearly envisage what specific perhydroxyl radicals, hydrogen peroxide, or hydroperoxide radicals hydrates were in applicants' possession, the only reasonable conclusion said artisan would make was that applicants were not in possession of hydrates of perhydroxyl radicals, hydrogen peroxide, or hydroperoxide radicals and had not reduced to practice the preparation, isolation, and characterization of said hydrates.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-4, 6, 9-11, 13 & 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldstein et al. (WO 96/032120, provided by applicant on IDS, machine translation enclosed).

Claim 1: Goldstein et al. disclose a combination of oxygen anion radicals (a substance active in the nasal mucous membrane) with opiate and non-opiate analgesics (active agents affecting the central nervous system) in a form that lowers the

dosage of active agent needed to achieve the same response (potentiating the efficacy, paragraphs 15 & 16).

Claim 2: Goldstein et al. disclose the potentiation is attained by opiate and non-opiate analgesics (paragraphs 15 & 16).

Claim 3: Goldstein et al. disclose that the potentiation was observed with both superoxide (a free radical) and hydrogen peroxide (a radical former, paragraph 19 and example 8, paragraphs 49-53).

Claim 4: Goldstein et al. disclose the potentiation was observed with hydrogen peroxide (paragraph 19).

Claim 6: Goldstein et al. disclose using vasodilators in the pharmaceutical administration (paragraph 31).

Claims 9 & 10: Goldstein et al. disclose administering the active agent in a dose of 1mg/kg, which would place the average human dose within the claimed range (example 1, paragraph 33).

Claim 11: Goldstein et al. disclose the administration of metamizol (paragraph 30 and example 3, paragraphs 39 & 40).

Claim 13: Goldstein et al. disclose the administration of active agents in liposomes (paragraph 13).

Claim 14: Since Goldstein et al. disclose administering active agents in liposomes (paragraph 13), Goldstein et al. necessarily disclose active agents in forms other than solution.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 1, 7, & 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein et al. (WO 96/032120, provided by applicant on IDS, machine translation enclosed).

**Applicant claims**

Applicant claims a pharmaceutical comprising an active ingredient and a radical oxygen species.

**Determination of the scope and content of the prior art  
(MPEP 2141.01)**

Goldstein et al. teach, as a whole, pharmaceutical administration of active agents and radical oxygen species.

Since all other claims depend from claim 1, rejection of claim 1 under 35 USC 103 is also appropriate. Detailed discussion of the rejection of claim 1 and the teachings of Goldstein et al. appears discussed above.

Claims 7 & 8: Goldstein et al. teach administering the oxygen anion radicals (substances active in the nasal mucous membrane) in a flow rate of 1 fmol/s to 100 pmol/s (paragraph 14).

**Ascertainment of the difference between the prior art and the claims  
(MPEP 2141.02)**

The difference between the instant claims and Goldstein et al. is that Goldstein et al. do not expressly embody all claim limitations.

**Finding of *prima facie* obviousness  
Rationale and Motivation (MPEP 2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the flow rate of active applied to the nasal

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mucosal membrane as taught by Goldstein et al., because changing the flow rate effects the active agent dosage amount and dosage amounts are result-effective parameters that may be routinely optimized, and produce the instant invention. The skilled artisan would be motivated to optimize this flow rate to achieve a concentration commensurate with a desired effect. Further the teachings of Goldstein et al. create a reasonable expectation of success for the reasons stated above. Though applicants provide data, nothing in the data is unexpected based on the teachings of Goldstein et al.

15. Claims 1 & 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein et al. (WO 96/032120, provided by applicant on IDS, machine translation enclosed) in view of Garvey et al. (US Patent 5,703,073).

#### **Applicant claims**

Applicant claims a pharmaceutical comprising an active ingredient and a radical species.

#### **Determination of the scope and content of the prior art (MPEP 2141.01)**

Goldstein et al. teach, as a whole, pharmaceutical administration of active agents and radical oxygen species.

Since all other claims depend from claim 1, rejection of claim 1 under 35 USC 103 is also appropriate. Detailed discussion of the rejection of claim 1 and the teachings of Goldstein et al. appears discussed above.

**Ascertainment of the difference between the prior art and the claims  
(MPEP 2141.02)**

The difference between the instant claims and Goldstein et al. is that Goldstein et al. do not expressly teach nitrogen monoxide as free radical former active in the nasal mucous membrane. This deficiency in Goldstein et al. is cured by the teachings of Garvey et al.

Garvey et al. teach, as a whole, compositions and methods of preventing toxicity caused by the breakdown of NSAIDs (through NO radical damage).

Claim 5: Garvey et al. teach that Nitrogen monoxide (in all its forms) is capable of forming NO radicals (column 20, line 52 through column 21, lines 18).

**Finding of *prima facie* obviousness  
Rationale and Motivation (MPEP 2142-2143)**

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to substitute NO for the oxygen radical former in the pharmaceutical of Goldstein et al., as suggested by Garvey et al., and produce the instant invention, because NO is capable of forming NO radicals as are the pharmaceuticals disclosed by Goldstein. The skilled artisan would have been motivated to make this substitution because NO is a well known radical former and it would have

been obvious to the skilled artisan to substitute NO for an oxygen radical species as they both form radicals. Further the teachings of Goldstein et al. create a reasonable expectation of success for the reasons stated above. Though applicants provide data, nothing in the data is unexpected based on the teachings of Goldstein et al.

16. Claims 1 & 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein et al. (WO 96/032120, provided by applicant on IDS, machine translation enclosed) in view of Broccardo et al. ("Pharmacological Data On Dermorphins, A New Class Of Potent Opioid Peptides From Amphibian Skin" *Br. J. Pharmac.* (1981), vol. 73, p. 625-631).

#### **Applicant claims**

Applicant claims a pharmaceutical comprising an active ingredient and a radical oxygen species.

#### **Determination of the scope and content of the prior art (MPEP 2141.01)**

Goldstein et al. teach, as a whole, pharmaceutical administration of active agents and radical oxygen species.

Since all other claims depend from claim 1, rejection of claim 1 under 35 USC 103 is also appropriate. Detailed discussion of the rejection of claim 1 and the teachings of Goldstein et al. appears discussed above.

Claim 12: Goldstein et al. teach opiate analgesics in the pharmaceutical (paragraph 16).

**Ascertainment of the difference between the prior art and the claims  
(MPEP 2141.02)**

The difference between the instant claims and Goldstein et al. is that Goldstein et al. do not expressly teach dermorphin. This deficiency in Goldstein et al. is cured by the teachings of Broccardo et al.

Broccardo et al. teach, as a whole, opioid peptides derived from amphibian skin.

Claim 12: Broccardo et al. teach dermorphin as an opioid analgesic (abstract and discussion, p. 630). Broccardo et al. also teach that dermorphin is more potent and less addictive than morphine (discussion, p. 630).

**Finding of *prima facie* obviousness  
Rationale and Motivation (MPEP 2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to substitute dermorphin for other opiates in the pharmaceutical of Goldstein et al., as suggested by Broccardo et al., and produce the instant invention, because dermorphin is more potent and less addictive than morphine. The skilled artisan would have been motivated to make this substitution because dermorphin is more potent and less addictive than other opiates. Additionally the selection of a substance known for a particular purpose is obvious to the skilled artisan. Further the teachings of Goldstein et al. create a reasonable expectation of success. Though applicants provide data, nothing in the data is unexpected based on the teachings of Goldstein et al.

17. Claims 1 &15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein et al. (WO 96/032120, provided by applicant on IDS, machine translation enclosed) in view of Veronesi et al. (US PreGrant Publication 2005/0158247).

**Applicant claims**

Applicant claims a pharmaceutical comprising an active ingredient and a radical oxygen species.

**Determination of the scope and content of the prior art  
(MPEP 2141.01)**

Goldstein et al. teach, as a whole, pharmaceutical administration of active agents and radical oxygen species.

Since all other claims depend from claim 1, rejection of claim 1 under 35 USC 103 is also appropriate. Detailed discussion of the rejection of claim 1 and the teachings of Goldstein et al. appears discussed above

Claims 15 & 16: Goldstein et al. teach that the oxygen anion radicals are only meta-stable (paragraph 12).

Claim 17: Goldstein et al. teach administration by inhalation or intranasal administration (paragraph 14).

**Ascertainment of the difference between the prior art and the claims  
(MPEP 2141.02)**

The difference between the instant claims and Goldstein et al. is that Goldstein et al. do not expressly teach auxiliary substances or the form of an endonasal spray. This deficiency in Goldstein et al. is cured by the teachings of Veronesi et al.

Veronesi et al. teach, as a whole, a nasal spray containing peptide active agents.

Claim 15 & 16: Veronesi et al. teach including a stabilizer in a nasal spray to keep the active ingredients from decomposing (paragraphs 16-20).

Claim 17: Veronesi et al. teach formulating the active agent in a spray for endonasal administration (claims 10 & 13).

**Finding of *prima facie* obviousness**  
**Rationale and Motivation (MPEP 2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add auxiliary substances to or formulate as a nasal spray the pharmaceutical of Goldstein et al., as suggested by Veronesi et al., because these additions and the dosage form will improve overall performance of the pharmaceutical, and produce the instant invention. The skilled artisan would have been motivated to make these additions and formulations because the Veronesi et al. teach that auxiliary substances will increase the storage life and delivery profile of the active agents and formulating the pharmaceutical as an endonasal spray is an effective method of delivery. Though applicants provide data, nothing in the data is unexpected based on the teachings of Goldstein et al.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re*

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*Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

#### ***Double Patenting***

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 1 & 16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 23 & 33 of copending Application No. 11/579,208 (the '208 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '208 application are species of the instant claims wherein the claims of the '208 application more narrowly define the compounds active in the nasal mucous membrane. Since the claims of the '208 application are species of the instant claims, they anticipate the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

Claims 1-17 are rejected. Claims 7 & 8 are objected to. Specification objected to.  
No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Lea whose telephone number is (571)270-5870. The examiner can normally be reached on Mon-Thu 7:30-5:00 ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CRL

/Johann R. Richter/  
Supervisory Patent Examiner, Art Unit 1616